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FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER
LLP

901 NEW YORK AVENUE, NW
WASHINGTON, DC 20001-4413

EXAMINER

LUCAS, ZACHARIAH

ART UNIT

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/561,345	Applicant(s) KRUPKA, UDO	
	Examiner Zachariah Lucas	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-30 and 33-51 is/are pending in the application.
- 4a) Of the above claim(s) 26,27,36-39,41,43-45,49 and 50 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24,25,29 and 46 is/are allowed.
- 6) ☒ Claim(s) 28,30,33-35,40,42 and 51 is/are rejected.
- 7) ☒ Claim(s) 29,47 and 48 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 24-30 and 33-51 are pending in the application.
2. In the prior action, mailed on June 8, 2009, claims 24-30 and 33-42 were pending; with claims 36-39 and 41 withdrawn from consideration; and claims 24-28, 30, 33-35, 40, and 42 under consideration and rejected; and claim 29 under consideration and objected to.
3. In the Response of October 8, 2009, the Applicant amended claims 24-28, 30, 33, 34, 40, and 42; and added claims 43-51.

Election/Restrictions

4. It is noted that, in the restriction requirement of June 11, 2008, the Applicant was required to elect one, or a combination of, the positions identified in claim 28, now included in claim 24. In the submission of August 11, 2009, the Applicant elected a species of the invention comprising amino acid of position 73 of SEQ ID NO: 12 (position 115 of HBV variant HDB 05). The Applicant determined not to elect a combination of such positions. Thus, combinations of the various positions are presently considered non-elected species until such time as the elected species is found allowable or cancelled.

As amended or presented, claims 26, 27, 43-45, 49, and 50 read on such non-elected species, and are therefore withdrawn from consideration.

It is noted that, in view of the amendments to the claims, examination has been extended to additional species of the claimed inventive group.

5. Claims 24, 25, 28-30, 33-35, 40, 42, 46-48, and 51 are under consideration.

Specification

6. **(New Objection)** The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the specification lacks antecedent basis support for the limitations of (e.g.) claim 28 with respect to the positions of SEQ ID NO: 12 in which the claimed fragments must be found. The specification appears to provide descriptive support for this group of fragments of SEQ ID NO: 12 on lines 29-33 of page 12 (teaching fragments of the sequence including the indicated positions and having 8 consecutive amino acid positions of SEQ ID NO: 12). It is noted that positions 66-80 represent the entire region in which 8 amino acid fragments of SEQ ID NO: 12 comprising position 73 of that sequence may be found. However, the specification does not provide antecedent basis for the language referring to this region presented in the amended claims.

It is suggested that the claim language be inserted into the teachings on pages 12-13 of the specification.

Claim Objections

7. **(Prior Objection- Withdrawn)** Claim 28 was objected to due to informalities. In view of the amendment of the claim, the objection is rendered moot, and is therefore withdrawn.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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9. **(Prior Rejection- Withdrawn)** Claims 28, 30, 33-35, 40, and 42 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The rejection was on three grounds. The first two grounds applied to claims 28, 30, 33-35, 40, and 42. In view of the amendment of claim 28, these grounds of rejection are withdrawn.

In addition, and third ground of rejection was made with respect to claims 33-35, 40, and 42 for depending from a cancelled claim. In view of the amendment of these claims, this portion of the rejection is also withdrawn.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. **(Prior Rejection- Withdrawn)** Claims 25, 27, 40, and 42 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. In view of the amendments to the claims, the rejection is withdrawn.

12. **(Prior Rejection- Withdrawn)** Claims 24, 26, 33-35, 40, and 42 were rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polypeptides comprising SEQ ID NO: 13, does not reasonably provide enablement for the use of any polypeptide comprising an amino acid sequence of at least 94% identity to that sequence. In view of the amendments to the claims, the rejection is withdrawn.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. **(Prior Rejections- Withdrawn)** Claims 28, 33-35, and 40 were rejected under 35

U.S.C. 102(b) as being anticipated by Langley et al. (EP 0533492). Claim 28 was rejected under 35 U.S.C. 102(b) as being anticipated by GenPept BAC17521. In view of the amendments to the claims, the rejections are withdrawn.

15. **(New Rejection- Necessitated by Amendment)** Claims 28, 30, 33, 40, and 51 are rejected under 35 U.S.C. 102(a) as being anticipated by GenBank AAO41333. Claims 28, 33, 40, and 51 read on a polypeptide comprising a fragment of SEQ ID NO: 12, the fragment comprising at least 6 amino acids found within the sequence of residues 107-117 of SEQ ID NO: 12 and comprising the amino acid of position 112 of SEQ ID NO: 12 (L112). This sequence of residues 107-117 is found in residues 323-333 of the sequence disclosed by the indicated GenBank sequence. Claim 30 requires that the polypeptide reacts to sera from a patient infected with HBV variant HDB 05. Because the sequence disclosed by the reference includes the sequence of claim 28, the sequence would also be capable of reacting to sera directed to the shared sequence, and thus meets the requirements of claim 30. The reference therefore anticipates the indicated claims.

It is noted that the reference has a publication date after the foreign priority date claimed by the present application. However, Applicant cannot rely upon the foreign priority papers to

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overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

16. **(New Rejection- Necessitated by Amendment)** Claims 28, 30, 33, 40, and 51 are rejected under 35 U.S.C. 102(b) as being anticipated by GenBank AAF36498. Claims 28, 33, 40, and 51 read on a polypeptide comprising a fragment of SEQ ID NO: 12, the fragment comprising at least 6 amino acids found within the sequence of residues 117-127 of SEQ ID NO: 12 and comprising the amino acid of position 122 of SEQ ID NO: 12 (V122). Claim 30 has been described above. The indicated sequence of SEQ ID NO: 12 is found in positions 159-169 of the GenBank sequence. The reference therefore anticipates the indicated claims.

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

18. Claims 34, 35, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over either of GenBank AAO41333 or GenBank AAF36498 as applied above, and further in view of U.S. 5,856,084. These claims read on methods for the recombinant expression of the claimed proteins or the use of such for the detection of anti-HBV antibodies.

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The GenBank references teach HBV S and pre-S proteins comprising the claimed HBV S antigen sequences. However, the reference does not teach the methods of the presently rejected claims.

The patent teaches that the HBV S and pre-S antigens are useful in immunoassays, including assays for the detection of anti-HBV antibodies. Cols. 1-2, and 8. While the teachings of the patent are specifically directed to the use of particular HBV mutant S antigens, it would have been apparent to those of ordinary skill in the art that the unmodified proteins of the GenBank references could also be used in such methods. In view of such teachings, it would have been obvious to those of ordinary skill in the art that the antigens of the GenBank references could be used as HBV antigens in such assays.

In addition, the patent also teaches that HBV antigens may be recombinantly expressed through methods such as those described by claims 34 and 35. See e.g., column 7. It would therefore also have been obvious to those of ordinary skill in the art to use such methods for the production of the HBV proteins of the GenBank references.

The presently claimed methods are therefore obvious over the teachings of the prior art.

Double Patenting

19. Claims 47 and 48 objected to under 37 CFR 1.75 as being a substantial duplicates, respectively of claim 25 and 46. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is

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proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Conclusion

20. Claims 24, 25, 29, and 46 appear to be allowable over the prior art. Claim 29 is objected to for depending from a rejected claim.

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is (571)272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert B. Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zachariah Lucas/
Primary Examiner, Art Unit 1648